ICS 35.240.80 SLOVENSKÁ TECHNICKÁ NORMA Január 2016

STN	**Funkčný model systému elektronického zdravotného záznamu (ISO/HL7 10781: 2015).**	**STN EN ISO 10781** 84 8102

Health Informatics - HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM) (ISO 10781:2015)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/15

Obsahuje: EN ISO 10781:2015, ISO/HL7 10781:2015

Oznámením tejto normy sa ruší
STN EN ISO 10781 (84 8102) z apríla 2010

122152

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10781

August 2015

ICS 35.240.80

Supersedes EN ISO 10781:2009

English Version

Health Informatics - HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM) (ISO 10781:2015)

Informatique de santé - Modèle fonctionnel d'un système de dossier de santé électronique, publication 2 (EHR FM) (ISO 10781:2015)

Funktionales Modell für ein elektronisches Gesundheitsaktensystem (EHRS FM), Ausgabe 2 (ISO 10781:2015)

This European Standard was approved by CEN on 30 April 2015.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

European foreword

This document (EN ISO 10781:2015) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10781:2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10781:2015 has been approved by CEN as EN ISO 10781:2015 without any modification.

INTERNATIONAL STANDARD

ISO 10781

Second edition
2015-08-01

Health Informatics — HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM)

Informatique de santé — Modèle fonctionnel d'un système de dossier de santé électronique, publication 2 (EHR FM)

Reference number
ISO 10781:2015(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/HL7 10781 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/HL7 10781:2009), which has been technically revised.

Introduction

Information for readers

EHR System Functional Model Release 2.0 is based on a series of predecessors, starting in 2004 with the release of the first consensus Draft Standard, followed in 2007 by Release 1, then in 2009 with Release 1.1, jointly balloted with ISO/TC 215 and CEN/TC 251. Release 2.0 reflects many changes, including ballot comments that had been made on past ballots and where the HL7 EHR Work Group had committed to bringing consideration of requested changes forward. It also includes comments that were considered for future use from the ISO ballot of 2009 as well as considerations of the Comment Only ballot that was circulated in May 2011.

Other inclusions were made as a result of the multiple EHR System Functional Profiles that have been written on Functional Model Releases 1 and 1.1. There was great learning in those various domain as well as companion profiles. The EHR-S FM also incorporated two other Draft Standards for Trial Use: HL7 EHR Lifecycle Model and HL7 EHR Interoperability Model.

Changes from previous Release

The HL7 EHR-System Functional Model Release 2 had its first normative ballot in May 2012. The key changes as a result of the first normative ballot included the following.

- Moved the normative parts of the Glossary into the Conformance clause section as use of glossary consistently is key to ease in reading and understanding the model.
- Improved consistency in representation of Headers, Functions and Conformance Criteria throughout the model.
- Updated the conformance clause for ease of reading especially as it related to the different types of profiles: domain profiles and companion profiles.
- Provided clarity for functional description and related conformance criteria.
- Updated the content to be more current.

To see all of the comments and reconciliation of the Normative 1 ballot, please see the HL7 Ballot Website for the ballot cycle of May 2012.

Background

What are Electronic Health Record Systems?

The effective use of information technology is a key focal point for improving healthcare in terms of patient safety, quality outcomes, and economic efficiency. A series of reports from the US Institute of Medicine (IOM) identifies a crisis of “system” failure and calls for “system” transformation enabled by the use of information technology. Such a change is possible by “an infrastructure that permits fully interconnected, universal, secure network of systems that can deliver information for patient care anytime, anywhere.”(HHS Goals in “Pursuing HL7 EHR Functional Standard” in Memorandum to HIMSS from C. Clancy and W. Raub co-chairs of HHS Council on the Application of Health Information Technology, dated November 12, 2003.) A critical foundational component for resolving these system and infrastructure issues is the Electronic Health Record System (EHR-S).

In developing this EHR-S Functional Model, HL7 relied on three well-accepted definitions: two provided by the US. Institute of Medicine and one developed by the European Committee for Standardization/ Comité Européen de Normalization (CEN). This Functional Model leverages these existing EHR-S definitions and does not attempt to create a redundant definition of an EHR-S.

Existing EHR System Definitions

The IOM's 1991 report, The Computer-Based Patient Record: An Essential Technology, and updated in 1997 (Dick, R.S, Steen, E.B., and Detmer, D.E. (Editors), National Academy Press: Washington, DC) defined an EHR System as follows.

- The set of components that form the mechanism by which patient records are created, used, stored, and retrieved.
- A patient record system is usually located within a health care provider setting. It includes people, data, rules and procedures, processing and storage devices (e.g. paper and pen, hardware and software), and communication and support facilities.
- The 2003 IOM Letter Report, Key Capabilities of an Electronic Health Record System, defined the EHR System as including:
- Longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or health care provided to an individual.
- Immediate electronic access to person- and population-level information by authorized, and only authorized, users.
- Provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care.
- Support of efficient processes for health care delivery.

The 2003 ISO/TS 18308 references the IOM 1991 definition above as well as ISO 13606:

- A system for recording, retrieving and manipulating information in electronic health records.

How were the Functions Identified and Developed?

To achieve healthcare community consensus at the outset, the functions are described at a conceptual level, providing a robust foundation for a more detailed work. Functions were included if considered essential in at least one care setting. Written in user-oriented language, the document is intended for a broad readership.

Functional Granularity is a term used to describe the level of abstraction at which a function is represented. Functions that are commonly grouped together in practice or by major systems have been consolidated where appropriate; functions requiring extra or separate language or involving different workflows have been kept separate where appropriate. For example, decision support is maintained as a separate section, but mapped to other key sections, to indicate the "smart" function behind an action. All of the functions could be expanded into more granular elements but a balance between a usable document and an unwieldy list of functions has been agreed upon. The goal of determining an appropriate level of functional granularity at this time is to present functions that can be easily selected and used by readers of this standard, but that are not so abstract that readers would need to create a large number of additional functions within each function.

Although the determination of functional granularity is a relatively subjective task, systematic evaluation of each function by diverse groups of industry professionals has resulted in a level of granularity appropriate for this EHR-S Functional Model. Every attempt has been made to provide supporting information in the functional descriptions to illustrate the more granular aspects of functions that may have been consolidated for usability purposes.

Keeping with the intent of this EHR-S Functional Model to be independent with regard to technology or implementation strategy, no specific technology has been included in the functions, but may be used in the examples to illustrate the functions. Inclusion of specific technologies in the examples does not endorse or support the use of those technologies as implementation strategies.

Drafts of the EHR-S Functional Model and of specific functions have been widely reviewed by healthcare providers, vendors, and other stakeholders. This proposed standard reflects input from all these reviewers.

INTERNATIONAL STANDARD **ISO 10781:2015(E)**

Health Informatics — HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM)

1 Scope

The HL7 EHR System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Functional Model, through the creation of Functional Profiles for care settings and realms, enables a standardized description and common understanding of functions sought or available in a given setting (e.g. intensive care, cardiology, office practice in one country or primary care in another country).

The HL7 EHR-S Functional Model defines a standardized model of the functions that may be present in EHR Systems. From the outset, a clear distinction between the EHR as a singular entity and systems that operate on the EHR, i.e. EHR Systems, is critical. Section 1.1.3 describes the basis and foundation for the HL7 definition of an EHR System. Notably, the EHR-S Functional Model does not address whether the EHR-S is a system-of-systems or a single system providing the functions required by the users. This International Standard makes no distinction regarding implementation; the EHR-S described in a Functional Profile may be a single system or a system of systems. Within the normative sections of the Functional Model, the term “system” is used generically to cover the continuum of implementation options. This includes “core” healthcare functionality, typically provided by healthcare-specific applications that manage electronic healthcare information. It also includes associated generic application-level capabilities that are typically provided by middleware or other infrastructure components. The latter includes interoperability and integration capabilities such as location discovery and such areas as cross application workflow. Interoperability is considered both from semantic (clear, consistent and persistent communication of meaning) and technical (format, syntax and physical connectivity) viewpoints. Further, the functions make no statement about which technology is used, or about the content of the electronic health record. The specifics of ‘how’ EHR systems are developed or implemented is not considered to be within the scope of this model now or in the future. This EHR-S Functional Model does not address or endorse implementations or technology, nor does it include the data content of the electronic health record.

Finally, the EHR-S Functional Model supports research needs by ensuring that the data available to researchers follow the required protocols for privacy, confidentiality, and security. The diversity of research needs precludes the specific listing of functions that are potentially useful for research.

This Functional Model is not:

— a messaging specification;

— an implementation specification;

— a conformance specification;

— an EHR specification;

— a conformance or conformance testing metric;

— an exercise in creating a definition for an EHR or EHR-S.

The EHR-S Functional Model is not sufficient to provide a longitudinal health record; however, it will contribute to its development. The information exchange enabled by the EHR-S supports the population of clinical documents, event summaries, minimum data sets, claims attachments, and in the future will enable a longitudinal health record.

Additionally, it is important to note that the EHR-S Function Model does not include a discussion of clinical processes or the interaction of the healthcare actors. However, ISO 13940 is an international standard that does outline key principles and processes in the provision of healthcare. Users of the EHR-S FM can refer to ISO 13940 for clinical processes that EHR systems support.

This EHR-S Functional Model package includes both Reference and Normative sections.

Table 1 — Normative Status Types

Status	Description
Reference	Content of the EHR-S Functional Model Package that contains information which clarifies concepts or otherwise provides additional information to aid understanding and comprehension. Reference material is not balloted as part of the standard.
Normative	Content that is part of the EHR-S Functional Model which HL7 committee members and interested industry participants have formally reviewed and balloted following the HL7 procedures for Balloting Normative Documents. This HL7 developed Functional Model document has been successfully balloted as a normative standard by the HL7 organization.

Each section within this document is clearly labelled “Normative” if it is normative. For example, in Clause 7, Conformance Clause, subclauses 7.2 and 7.4 are normative.

In the external Annex A, Function List, the Function ID, Function Name, Function Statement, and Conformance Criteria components are Normative in this Functional Model.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TR 12773-1:2009, *Business requirements for health summary records — Part 1: Requirements*

ISO/TS 13606-4:2009, *Health informatics — Electronic health record communication — Part 4: Security*

ISO/TS 17090-1:2002, *Health informatics — Public key infrastructure — Part 1: Framework and overview*

ISO 18308:2011, *Health informatics — Requirements for an electronic health record architecture*

ISO/IEC 2382-8:1998, *Information technology — Vocabulary — Part 8: Security*

ASTM E1769:1995, *Standard guide for properties of electronic health records and record systems*